REMARKS

In view of the above amendments and the following remarks, Applicants request reconsideration and allowance of the claims. Initially, Applicants wish to thank the Examiner for her helpful telephonic discussion regarding the claims and cited art of record. Applicants believe that the amendments to the claims respond to the Examiner's concerns.

Claims 21-23, 25-48 and 50-53 are pending with claims 21, 36, 39, and 47 being independent. Claims 21, 36, 39, and 47 have been amended. The amendments to the claims find support in the application as filed at least at page 27, line 26 through page 29. line 2, and Figures 76-79. In particular, Fig. 79 illustrates a cross-sectional view of a sheet of superelastic/shape memory material which illustrates the uniformity of the sheet 980. No new matter has been added with these amendments to the claims. Applicants respectfully request entry of the amendments to the claims as the amendments are believed to put the claims in condition for allowance and any searching required will not put any burden on the Examiner.

The Office Action requests new corrected drawings for Figures 6-11 and 20-25 for being crowded and unclear. The attached replacement sheets are believed to adequately address this requirement.

Claims 21-23, 27-30 and 34-36 have been rejected as being anticipated by Schmitt (US 6,375,662). As amended, claim 21 is directed to a medical device for placing against a tissue surface within a mammalian to close an opening in the tissue. The device includes at least one layer of a biocompatible material and at least one layer of a biocompatible superelastic/shape memory material. The biocompatible superelastic/shape memory material is in the form of a sheet having an upper side and a lower side, the sheet consisting of one piece of a single material and being covered over at least a portion of the upper side and at least a portion of the lower side by the biocompatible material without the use of an adherent material. The biocompatible superelastic/shape memory material is configured to have a curved configuration in an unconstrained shape if the biocompatible superelastic/shape memory material is configured to have a superelastic property or to have a curved configuration in a heated, transformed shape if the biocompatible superelastic/shape memory material is configured to have a shape memory property.

Schmitt is directed to woven patches that are placed against soft tissue while also being configured to provide increased resistance to bacterial infections that can occur in the interstices between fibers in the woven patch. Schmitt accomplishes this increased resistance by coating the fibers or filling the interstices with a polymer resin. See e.g., Fig. 2a. Schmitt notes that the patches can have a shape imparted by heating or using nitinol threads. See column 8, lines 19-34 ("The mesh could also include individual threads having a shape-memory imparted thereto, such as nitinol threads.").

Schmitt, however, fails to describe or suggest the medical device of claim 21 having: (1) a sheet of a superelastic/shape memory material having an upper side and a lower side, the sheet consisting of one piece of a single material, or (2) the sheet being covered over at least a portion of the upper side and at least a portion of the lower side by the biocompatible material without the use of an adherent material.

First, Schmitt discloses using a multifilament yarn surrounded by a resin. Schmitt states that "[]the mesh could also include individual threads having a shape memory imparted thereto, such as nitinol threads." See column 8, lines 19-35. Nonetheless, a composite material of a resin, a multifilament yarn, and individual threads of a shape memory material cannot be compared to a sheet consisting of one piece of a single material, as recited in claim 21. As illustrated in Schmitt's Fig. 2a through Fig. 7a, Schmitt's meshes are a composite material of more that one piece of a single material. For example, the meshes are made up of multiple pieces (e.g., multifilament yarns, see col. 4, lines 64-67) and more than a single material (i.e., the yarn and the resin).

Second, claim 21 recites the polymer covering portions of the superelastic/shape memory material without the use of an adherent material. In contrast, Schmitt uses resins that appear to adhere to the filaments. For example, Schmitt discloses polymer resins that are applied to the trellis of yarn as a hot melt (column 5, lines 37-47), as a resin solution in a solvent that is evaporated off (column 5, lines 48-51), and as a sheath around the fibers such that trellis can be heated to fuse the resin-based sheaths together (column 6, lines 7-21 and 27-38). Thus, Schmitt appears to be using adherent materials for his resin to fill the interstitial spaces between the fibers as well as covering the fibers (Figs 3, 3a, 4, 4a).

The Office Action dated May 15, 2007 states that the threads form a sheet of woven material that is substantially flat and additional components aid in forming the threads into the sheet. As Applicants understand Schmitt, those additional components are adherent materials, such as the resin. The Office Action dated May 15, 2007 further states that the resin is what makes up the layer of biocompatible material. According to Schmitt's figures (e.g., Figs. 2a-7a) the resin (an adherent material) surrounds the yarn and adheres to the yarn. Thus, in contrast to Applicants' claim 21, Schmitt describes the use of an adherent material, and only an adherent material, to cover the sheet of threads or yarn.

For at least these reasons, claim 21 and dependent claims 22, 23, 27-30, 34 and 35 are allowable over Schmitt.

Independent claim 36 also has been rejected as being anticipated by Schmitt. Like claim 21, claim 36 recites a medical device having (1) a sheet of a superelastic/shape memory material having an upper side and a lower side, the sheet consisting of one piece of a single material, and (2) the sheet being covered over at least a portion of the upper side and at least a portion of the lower side by the biocompatible material without the use of an adherent material. Thus, for the same reasons that claim 21 is allowable over Schmitt, claim 36 is allowable over Schmitt.

Claims 25, 26, 31-33, 37-41, 43-48, and 50-53 are rejected as being obvious over Schmitt in view of one or more of King (US 3,874,388), Forber (US 5,733,294), Zhu (US 6,589,269), Evard (US 5,536,251) and Hammerslag (US 5,653, 730).

King is directed to umbrella-like devices that are implanted through a catheter to close an opening in the cardiovascular system, such as a ventricular septal defect or a patent ductus arteriosus. The device includes a pair of umbrella like portions that expand once outside of the catheter. Much like the configuration of an umbrella, the umbrella-like portions of the disclosed device include struts and a fabric that is tied to the struts (reference numerals 81, 91). See Figs. 1c and 4. The struts are described as being made of a radiopaque material but not necessarily being metal. However, King fails to cure the deficiency of Schmitt to describe or suggest a medical device having a sheet of a superelastic/shape memory material having an upper side and a lower side and being covered over at least a portion of the upper side and at least a portion of

the lower side by the biocompatible material. In particular, King does not disclose a sheet of superelastic/shape memory material but instead discloses what appears to be rod to form the struts. See Figure 2A. Moreover, King does not describe or suggest the fabric covering at least a portion of both the upper side and the lower side of the strut. Instead, the fabric is tied to the struts such that only a single side of the strut is covered.

Forber is directed to self-expanding cardiovascular occlusion devices used to occlude vessels and aneurysms. The devices are self-expanding and included a predetermined pattern of wire and collinear bands encircling the wire such that pushing the bands together causes two exposed braided or helical sections between them to flatten out for delivery through a catheter. After being released from the catheter, the device expands to fill an area of the vasculature, causes a clot to form, and ultimately results in an occlusion. The materials disclosed for making the wires includes superelastic materials such as nitinol. Forber states that filaments also can be positioned to extend from the bands. However, Forber fails to cure the deficiency of Schmitt to describe or suggest a medical device having a sheet of a superelastic/shape memory material having an upper side and a lower side, the sheet consisting of one piece of a single material and being covered over at least a portion of the upper side and at least a portion of the lower side by the biocompatible material.

First, Forber's only disclosure of superelastic materials relates to its use in the wires. Like Schmitt, Forber does not disclose a sheet of a superlelastic/shape memory material consisting of one piece of a single material. In addition, Forber does not disclose the wires having an upper side and a lower side being covered over at least a portion of the upper side and at least a portion of the lower side by the filaments.

Zhu discloses a patch and glue delivery system for applying a patch to close a tissue opening. The description of the patch is limited to a brief listing of its materials:

> The patch 60 is adapted to cover an opening in body tissue and may be shaped in any desired geometry and formed from any suitable patch material, such as PTFE, biovascular material, collagen, Gore-Tex®., Dacron®, etc. The patch may also be formed out of materials that will dissolve over time within the patient's body.

Thus, Zhu's patch cannot be characterized as having a superelastic/shape memory material much less a sheet of a superelastic/shape memory material. As such, Zhu fails to cure the deficiency of Schmitt to describe or suggest a medical device having a sheet of a superelastic/shape memory material having an upper side and a lower side and being covered over at least a portion of the upper side and at least a portion of the lower side by the biocompatible polymer material.

Evard is directed to surgical instruments for minimally invasive cardiovascular surgery and references surgical staples and a patch for closing openings in tissue. Evard's patch is not described beyond noting that it can be used to close a penetration in the wall of the aorta where a delivery catheter had been placed. See column 3, line 66 through column 4, line 3. Thus, Evard fails to cure the deficiency of Schmitt to describe or suggest a medical device having a sheet of a superelastic/shape memory material having an upper side and a lower side and being covered over at least a portion of the upper side and at least a portion of the lower side by the biocompatible material.

Hammerslag is directed to methods of applying adhesives to seal openings in tissue and discloses the use of porous polymer patches with the tissue adhesive:

> Tissue adhesives of the type described above are well suited to seal a typical PTCA arterial perforation, which commonly has a non-dilated diameter of about 1 mm, where the arterial wall is relatively elastic. However, where the arterial wall is relatively inelastic, and the typical PTCA arterial perforation commonly has a non-dilated diameter of about 2-3 mm, it has been found desirable to use a porous patch 150 in combination with the tissue adhesive to further improve the integrity of the seal across the arterial perforation.
>
> [. . .]
>
> The patch 150 is preferably formed of a mesh, weave or knitted material which is biocompatible, and preferably is biodegradable (i.e., is absorbable within the body). The patch 150 can be formed of any of a wide variety of suitable materials, such as, for example, polytetrafluoroethylene (PTFE), oxidized regenerated cellulose, Gelfilm™ available from the Upjohn Co. and collagen. A suitable material from which to form the patch 150 is a sterile absorbable mesh material (either knitted or woven) available commercially as VICRYL™ from Ethicon (a Johnson and Johnson company) of Somerville, N. J.
>
> The patch 150 may be impregnated, coated, or otherwise pretreated at the point of manufacture with a tissue adhesive, such as, for example, any of the tissue

> adhesive types described above. In this manner, the adhesive coated surface of the patch 150 will adhere to the surface of the vessel surrounding the perforation upon application of the patch 150. Alternatively, the patch 150 and the tissue adhesive can be provided separately, and the patch 150 is saturated or coated with tissue adhesive at the time of application or just before application, as discussed below.

See column 11, lines 8-65. Hammerslag, however, does not describe or suggest that his patch may include a sheet of a superelastic/shape memory material much less a medical device having a sheet of a superelastic/shape memory material having an upper side and a lower side and being covered over at least a portion of the upper side and at least a portion of the lower side by the biocompatible material without the use of an adherent material.

Claims 25, 26, 31-33, 37-41, 43-48 and 50-53 are allowable over Schmitt in view of one or more of King, Forber, Zhu, Evard or Hammerslag, taken individually or in combination, because they fail to cure the deficiency of Schmitt to describe or suggest a medical device having a (1) a sheet of a superelastic/shape memory material having an upper side and a lower side, the sheet consisting of one piece of a single material, and (2) the sheet being covered over at least a portion of the upper side and at least a portion of the lower side by the biocompatible material without the use of an adherent material.

In conclusion, Applicants believe all claims are allowable and request a notice of allowance. The Examiner is urged to contact the undersigned should she have any questions. Although no charges are believed due, authorization is given to apply any charges or credits to Deposit Account No. 502923. Applicants claim a small entity status.

Respectfully submitted,

Date: August 15, 2007

/william hare/
William D. Hare
Reg. No. 44,739

William D. Hare
3 Anderson Lane
Princeton, NJ USA
Telephone: (609) 240-2533
Facsimile: (609) 945-4932